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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/828,668	04/21/2004	Igor Waysbeyn	H308-001-PAT	4917												
7590 Angenehm Law Firm Ltd. P.O. Box 48755 Coon Rapids, MN 55448-0755		10/29/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">MILLER, CHERYL L</td></tr></table> <table border="1"><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>3738</td><td></td></tr></table> <table border="1"><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>10/29/2007</td><td>PAPER</td></tr></table>		EXAMINER		MILLER, CHERYL L		ART UNIT	PAPER NUMBER	3738		MAIL DATE	DELIVERY MODE	10/29/2007	PAPER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,668

Applicant(s)

WAYSBEYN ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13, 15-24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 15-24, and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 11-28 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

Claims 18, 19, 20, and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Each claim includes a limitation that positively claims a portion of the body by a direct comparison, bodily parts considered non-statutory subject matter.

Claim 18 claims a cone having a profile corresponding to a profile of a vessel. It is suggested to change the above to describe a cone having a profile *sized to correspond or adapted to correspond* to the vessel profile.

Claim 19 claims a direct comparison of size to the vessel diameter wherein a cone has a smaller diameter than the vessel. The claim is positively claiming the size of a present vessel. It is suggested to change the above to describe a cone having a *diameter sized to be or adapted to be smaller* than the diameter of the vessel.

Claim 20 claims a direct comparison of the size of the vessel wherein a cone larger diameter surpasses a vessel diameter. The claim is positively claiming the size of a present vessel. It is suggested to change the above to describe a larger diameter of the cone is *sized to surpass or adapted to surpass* the inner diameter of the vessel.

Claim 22 positively claims the thickness of a vessel, wherein the barbs have a length longer than the thickness of the vessel. It is suggested to change the above to describe the barbs having a length *sized to be longer* than the thickness of the vessel.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-21, 23-24, and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is a Markush type claim and should include the language, "selected from the group consisting of" and also "and" instead of "or".

Claim 16 is indefinite. The claim recites, "docking heads comprise a hollow truncated cone". It is unclear whether this "cone" is a new additional cone or if it is referring to the "thin-walled truncated cone" of claim 11. Claims 17-21 and 26 depend upon claim 16 and inherit all problems with the claim.

Claim 23 recites the limitation "said hollow truncated cone" in line 3. There is insufficient antecedent basis for this limitation in the claim. The "hollow" portion has no antecedent basis.

Claim 24 recites the limitation "said hollow truncated cone" in line 3. There is insufficient antecedent basis for this limitation in the claim. The "hollow" portion has no antecedent basis.

Claim 27 is indefinite. The claim requires the cone to be everted over the docking head. This is unclear since independent claim 11 requires the cone to be part of the docking head. Since the docking head comprises a cone, it is unclear and indefinite how the cone may be everted onto itself. Also, independent claim 11 now requires the graft and docking heads to be separate components movable with respect to one another, and in this embodiment it is unclear how the docking head may be an extension of the graft. It seems this claim may be directed toward a different embodiment not combinable with the embodiment claimed in the independent claim and may be withdrawn in a subsequent action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 15-24, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (US 6,110,198). Fogarty discloses a device for treating an aneurysm (102; fig.5C) comprising a tubular graft (64) having a proximal and distal portions (two ends seen in fig.5C) and at least two docking heads (62, 66) comprising thin walled truncated cones (the heads are disclosed to be tapered or have flared ends, thus have truncated cone shaped ends; fig.3, 6b; col.9, lines 58-61; col.18 line 57-col.20 line 25) a first docking head (62) at a proximal portion of the graft and a second docking head (66) at a distal portion of the graft, wherein the docking heads are movable with respect to and adapted to be adjusted and fastened to the graft before implantation (col.11, lines 36-40; Fogarty's docking heads 62, 66, may be attached to graft 64 by

friction fit prior to implantation, and before attachment as they are separate components, they are movable with respect to one another), and a plurality of outwardly pointing and inclined barbs (83 or 85; figs.3b, 3c) connected to the docking heads (62, 66), the device capable of being coupled to a vessel on both sides of an aneurysm (102) by docking heads that act to guide, anchor and seal in a suture-less manner (stent of 62, 66 acts to anchor, the graft of 62, 66 acts to seal, and the proximal ends of 62, 66 act to guide into position as would the disclosed radiopaque markers that may be positioned on 62, 66).

Fogarty discloses the heads (62, 66) to be coupled to the graft (64) by fit. The docking heads are capable of and shown in the figures to be placed on either the inside or outside of graft and since the stents of the heads (62, 66) are expandable, they are capable of having many diameters smaller and larger than the graft and vessel wall. Fogarty's barbs (83) are flexible and inclined to the graft (see fig.3b). The barbs are shown to have a length *capable of* penetrating the vessel wall. Fogarty discloses barbs (85) that are concave and convex (the outer surface of 85 are convex and inner surface of 85 are concave). Fogarty discloses a hollow truncated cone (stent of 62 or 66) has a plurality of open slits (apertures between stent struts considered slits) which allow expansion. Fogarty discloses the graft (64) and docking heads (62, 66) to be separate modules that are capable of being selected prior to insertion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 13, 15-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (US 6,729,356 B1, cited previously). Baker discloses a vascular device (fig.1 for example) comprising a tubular graft (34) with proximal (top) and distal (bottom) ends, a first docking head (40+44) provided at the proximal end and a second docking head (disclosed to having multiple; col.4, lines 34-38) provided at the distal end. Baker discloses the graft (134) to be tubular and bifurcated (col.2, lines 9-14, 18-24). Baker discloses the docking heads (40+44) to be truncated cones in shape (see fig.1; col.5, lines 26-28). Baker's docking heads are moveable and adapted to be adjusted and fastened to the graft prior to insertion (Baker's docking heads 40 are separate components sewn to the graft prior to implantation, thus are moveable and adjustable prior to attachment, which occurs prior to implantation thus meets the claim). Baker discloses the device to be capable of coupling to both sides of an aneurysm (col.4, lines 34-41; see fig.18 for example, showing a different embodiment at such a location), the docking heads capable of acting to guide (position at the ends of the graft, will provides the guiding since located at the most proximal and distal ends), anchor (stent 44 provides anchorage), and seal (graft of 40 provides seal). Baker discloses the vascular device substantially as claimed, however does not disclose a plurality of inclined barbs on the docking heads. Baker does disclose the use of barbs (43) on other portions of the device, such as on stent (38) in order to anchor the device to the vessel wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to additionally or instead place barbs on the stent 44 of the docking heads, since such a modification would involve a mere relocation or duplication of parts. Barbs are already used on one stent (38) of Baker that contacts the vessel wall, it would be obvious to place barbs on the docking head stent (44) since the docking head also contacts the

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vessel and would provide predictable results of anchorage at another location on the device. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and also *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

Claims 11, 13, 15-22, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randall et al. (US 2003/0158575 A1, cited previously) in view of Fogarty (US 6,110,198). Randall discloses a vascular device (fig.6) comprising a graft (40) with proximal (top) and distal (bottom) ends, a first docking head (stent 10) provided at the proximal end and a second docking head (stent 16 or 18) provided at the distal end. Randall discloses the graft (40) to be tubular and bifurcated, see fig.6). Randall discloses the docking heads (10, 16, 18) to be capable of moving relative the stent (they are not disclosed to be sewn or adhered to the graft therefore are inherently capable of moving prior to expansion and insertion). Randall discloses attachment of the docking heads upon expansion, by clips/barbs that are inclined (14). Randall discloses the docking heads (10, 16, 18) to be separate modules than the graft (40). Randall discloses the device substantially as claimed however does not disclose the docking heads to be truncated cones. Fogarty teaches in the same field of vascular devices, the use of flared ends of stents (232, 112; see fig.6B, 6C, 5C, 15; considered “docking heads”; the flared shaped producing a truncated cone shape), for providing better anchorage and sealing to the vessel wall (specifically col.19, lines 8-10; col.18 line 57-col.20 line 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Fogarty’s teaching of flared stent ends (producing truncated cone shape) on the stents (“docking heads”10, 16, 18) of Randall, to provide an overall device with increased anchoring and sealing.

Claims 11, 15-20, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliot (US 2003/0236567 A1, cited previously) in view of Baker et al. (US 2002/0091439 A1). Elliot discloses a vascular device (figs.3a-3c) comprising a graft (12) with proximal (top) and distal (bottom) ends, a first docking head (16+22) provided at the proximal end and a second docking head (multiple docking heads, P0026) provided at the distal end, the docking heads being truncated conical in shape (see fig.3b, 3c). Elliot discloses the graft (12) to be tubular (see figs). Elliot discloses attachment of the docking heads by sutures or bonding (P0030), and are shown and disclosed to be separate modules attached sometime before implantation, therefore, are capable of relative movement and positioning prior to attachment and prior to insertion, since attachment does occur prior to insertion. Elliot discloses the cone (16) to be an extension of the graft everted over itself (fig.3b). Elliot discloses the docking heads to be capable of coupling to the vessel wall and capable of guiding (guides due to the positioning on the ends), anchoring (stent frame 22 provides anchorage) and sealing (graft skirt 16 provides sealing). Elliot discloses the vascular device substantially as claimed, however does not disclose the use of inclined barbs. Baker teaches in the same field of vascular devices, the use of inclined barbs (195; concave, convex, etc; figs.21-24) on docking heads (175, 176) in order to penetrate and attach a graft (55) to the vessel wall (P0095; P0098). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Baker's teaching of using inclined barbs (195) on docking heads (175, 176), with the docking heads (stent 22) of Elliot, in order to provide better anchorage to the vessel wall.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/



BRUCE SNOW
PRIMARY EXAMINER